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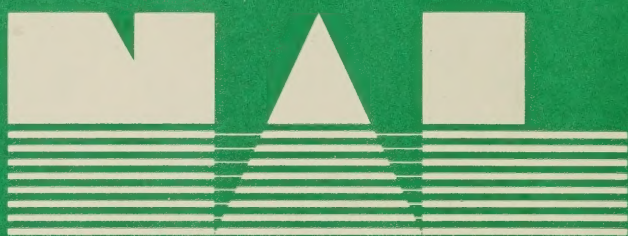
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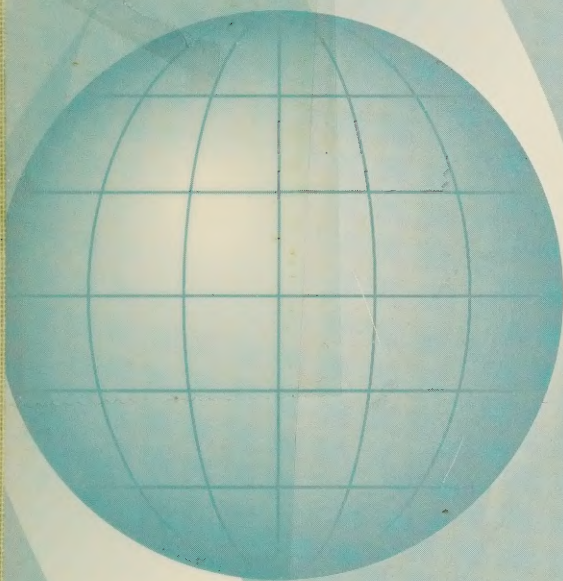
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# ance For U.S. Researchers Involved In International Exchange on Agricultural Biotechnology



# Foreword

How to balance the need for science to maintain an open process with the need to protect U.S. competitiveness, is one of the most important issues involving biotechnology today. As a world leader in agricultural biotechnology, the U.S. scientific community is increasingly being asked to share its biotechnology knowledge with foreign scientists.

This brochure offers some points to consider as guidance to U.S. researchers who are considering international scientific and technical exchanges. I would ask each member of the U.S. scientific community to consider them carefully. By making informed decisions on international exchanges involving biotechnology, we can ensure that U.S. farmers, businesses, and consumers derive the full benefits from our investment in this exciting area of research, while maintaining the openness which is fundamental to our scientific process.

*Charles E. Hess*

Charles E. Hess  
Assistant Secretary  
Science and Education



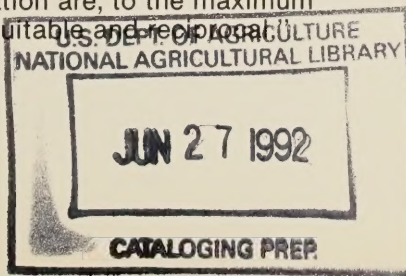


# Introduction

U.S. science has a long and proud tradition of openness that has contributed to its strength and success. The United States is recognized worldwide for sharing scientific knowledge, especially in basic research. In the last few years, however, observers both inside and outside the scientific community have been concerned that the United States may be losing ground in the competition for world markets. They see research results slipping away to foreign commercial development without adequate compensation. For agricultural biotechnology, the concern is reflected in two related issues:

- (1) Will sharing scientific knowledge allow other nations to increase agricultural production and displace U.S. food and fiber exports?  
and
- (2) Will U.S. developed technologies be used to produce biotechnology products abroad such as improved seeds, fertilizers, and insecticides without fair compensation to those who invested in their development?

Both the President of the United States of America and the U.S. Congress have focused on national competitiveness as a central issue in the 1980's and beyond. Considerable legislation and several executive orders have encouraged the transfer of U.S. Government basic research knowledge to private firms for product development. These directives require that Federal agencies, in consultation with the U.S. Trade Representative, closely monitor international activities to ensure that U.S. intellectual property rights are protected. Congress recently directed the U.S. Department of Agriculture (USDA) to screen all of its international activities to ensure that none have the potential for displacing U.S. agricultural exports. Furthermore, recent legislation called the 1988 Omnibus Trade and Competitiveness Act requires that "federally supported international science and technology agreements should be negotiated to ensure that (a) intellectual property rights are properly protected, and (b) access to research and development opportunities and facilities, and the flow of scientific and technological information are, to the maximum extent practicable, equitable and reciprocal."



Here are some specific procedures:

- Researchers in the USDA Agricultural Research Service (ARS) and Forest Service should contact their international program offices in Washington, D.C., before entering into cooperative programs.
- Some universities may require visiting scientists to sign agreements which specify the terms of their stay.
- All proposed activities submitted to the USDA Office of International Cooperation and Development (OICD) must have agency or university clearance. Proposals will be routinely screened for U.S. benefit and trade sensitivities by OICD, the Foreign Agricultural Service, and other USDA agencies before they are approved. OICD submits new agreements and major new activities with foreign countries to the U.S. Department of State, which coordinates an interagency review for scientific merit, equity of access, possible trade or commercial linkages, and national security concerns. In addition, every activity with Warsaw Pact Countries is sent for review.

**3) Is it the intention of the research to eventually commercialize the discoveries?**

Research is a spectrum of activity, ranging from basic to applied, with applied research leading to commercial applications. In most cases, it appears that basic research represents a good area of scientific exchange. Exchanges which deal with the more applied end of the research spectrum may compromise the commercialization of research discoveries in the United States. ARS and many universities have active programs to promote the patenting of biotechnology discoveries and technology transfer, including licensing arrangements with private firms. Public disclosure prior to filing a patent application may jeopardize the patent award and allow the technology to be used without compensation.

**4) Does the cooperating country have a record of respecting intellectual property rights?**

The emerging global economy makes protection of intellectual property rights increasingly important. As agreements for scientific and technical coopera-



tion between USDA and counterpart ministries of agriculture are negotiated or renewed, USDA is working with the Department of State, the Department of Commerce, and the U.S. Trade Representative to comply with recent legislation requiring more extensive protection of intellectual property rights. The National Science Foundation and other Federal agencies are also reviewing intellectual property rights provisions as part of their agreements with cooperating nations. Moreover, some universities are strengthening intellectual property rights in sections of their agreements with foreign institutions. Activities which occur outside formal agreements do not enjoy these protections and therefore should be approached more cautiously.

**5) Will the exchange foster safer experimentation?**

Exchanging knowledge on methods, procedures, protocols, and techniques for safe field testing with genetically engineered organisms is in everyone's best interest. Given the very modest opportunities for commercial advantage in biosafety research and the need to protect public health and the environment, the free and open exchange of information, especially in safe field testing, should be encouraged.

In some cases it may be safer and more effective to field test genetically engineered organisms abroad. This might occur when a particular pathogen does not exist in one country but is endemic in another. However, scientists should not participate in foreign field tests as a means of avoiding regulation, and in all cases they should follow safe practices for field testing. Such tests must also follow all of the regulations of the host country and any international guidelines which may apply.

**6) Does the exchange contribute to biodiversity?**

Genetic diversity is in the best interest of science and agricultural production. The exchange of genetic materials contributes to biodiversity and, hence, is an important consideration which should be considered when assessing reciprocity, especially when taken in the long-range view of agricultural science. Although tradition supports the open exchange of nonmodified organisms, U.S. scientists should exercise judgment when exchanging novel organisms

which may have commercial application. Again, reciprocity and the protection of intellectual property are keys. The regulations of the USDA Animal and Plant Health Inspection Service, the Centers for Disease Control, Department of Commerce, and U.S. Postal Service regarding movement must also be followed.

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## **Categories of Exchange Topics**

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### **Good Topics for Exchange**

Basic research attempts to understand the fundamental principles of a discipline and represents a good area for international scientific exchanges. The benefits of international exchanges in basic research are:

- A shared workload;
- Avoidance of duplication;
- Lower costs; and
- Assistance in verifying results.

For example, the mapping of plant and animal genomes requires a great deal of research time. By dividing the most important organisms among countries and then sharing the results, everyone stands to benefit. Short-term visits of principal investigators to the laboratories of others working in basic research can be very helpful in planning cooperative activities. Long-term visits, foreign graduate studies, and postdoctoral positions offer many opportunities to master complicated research methods and procedures.

Another area which offers good prospects for exchange is biosafety research. Sharing information on field test procedures with engineered organisms will promote the development of agricultural biotechnology in a responsible manner. Information exchanges will lead to a better understanding of the safety of biotechnology products and should diminish the possibility of nontariff trade barriers aimed at these products.

Finally, research aimed at improving the quality of life and the environment is considered a good area for international scientific exchanges in biotechnology. The prospects for cleaning up hazardous wastes and removing pollutants from soil, air, and water using genetically engineered organisms should be an international priority addressed through scientific exchanges. Exchanges might also focus on governmental procedures for ensuring compliance with environmental quality standards.

### **Exchanges Which Merit Careful Review**

Strategic research is categorically different from basic research in that it attempts to develop a broad-scoped effort to make major changes in an agricultural production system. An example of strategic research would be the modification of plants to grow in new agro-climatic zones. Sharing strategic research information internationally is a concern because of the potential for assisting U.S. trade competitors in displacing U.S. agricultural exports. Discoveries in strategic research that are given away may also compromise future patent protection. Scientists should proceed with caution in these exchanges and strongly weigh the benefits versus the potential costs to U.S. agriculture. If a scientist would like assistance in evaluating a proposal for exchange, the USDA Office of Agricultural Biotechnology (OAB) can help. This can be done informally by contacting the Director's office (see below). For complex questions, OAB may convene an *ad hoc* panel of experienced specialists from within USDA or refer the request to other appropriate Federal agencies such as the U.S. Trade Representative, Department of State, Department of Defense, or Department of Commerce.

### **Exchanges Which May Not Be Appropriate**

Applied and adaptive research are investigations aimed at developing the commercial uses of a nearly finished product, such as a crop variety, an improved animal breed, or a marketable drug. Sharing information at this stage of research has the potential for loss of commercial advantage for any research discoveries. As a general rule, exchange should not take place during the critical year prior to filing a patent application.



## **Exchanges Which Are Prohibited**

The U.S. Government prohibits the export of technology related to national security and defense, including disclosure to foreign nationals visiting the United States. This may apply not only to biological research, but also to such areas as computer technology and advanced instrumentation used to do the research. Although very little agricultural biotechnology research falls in this category, extreme caution should prevail.

## **Would You Like More Information?**

The Office of Agricultural Biotechnology would be pleased to review proposals for international scientific exchange and to provide assistance to researchers on any of the issues discussed in this brochure. Please contact:

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